510(k) SUMMARY

MAY 2 7 2011

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990and 21 CFR 807.92 at September 20, 2010.

The assigned 510(k) number is **K102935** .

1. Submitter's contact Information:

   Kingtech Enterprises Limited.
   FDA registration number: 3008808166
   Farm village, DaLingShan Town, DonGuan
   Phone: (86)769-8563-6260
   Fax: (86)769-8563-6234
   Official correspondent i.e. 510k contact person: Dr. Jen, Ke-Min
   Phone: (886)3-5208829
   Fax: (886)3-5209783
   E-mail: ceirs.jen@msa.hinet.net

2. Name of Device:

   Infrared Ear Thermometer, Models TM810A, TM810B, TM817, TM818, TM818A, TM819 and TM820

3. Information of the 510(k) Cleared Device (Predicate Device):

   Measure Technology, models: ST613C and ST614F (K011254)

4. Device Description:

   The Infrared Ear Thermometer, models TM810A, TM810B, TM817, TM818, TM818A, TM819 and TM820 is a handheld electronic thermometer that measures the temperature through the opening of the auditory canal by using a thermopile as the temperature sensor. The signal of sensor is calculated and displayed by an ASIC (Application Specific IC)- controlled circuit, which is considered the hard-wire control instead of programmable control.
   From the construction point of view, the ear thermometer comprised of a thermopile for the measuring sensor, a reference thermometer for comparison of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermopile sensor detect the ear canal temperature through the infrared.

   This system uses a 3.0V DC battery (2*AAA batteries) for operation of complete system whenever the battery is low, the ASIC circuit will detect the low battery condition automatically, and displays 'Low battery' in LCD display. Regarding the performance of TM810A, TM810B, TM817, TM818, TM818A, TM819 and TM820, they were designed and verified according to the US standard ASTM E 1965-2003.

5. Intended Use:

   The Infrared Ear Thermometer model TM810A, TM810B, TM817, TM818, TM818A, TM819 and TM820 are the battery-operated electronic devices with intended use of measuring body temperature from the auditory canal of a patient by means of an infrared sensor coupled with electronic signal amplification, conditioning and a digital LCD (display) unit. The device is a reusable and intended for home use on people at all ages.

6. Comparison to the 510(k)Cleared device (Predicate Device):

   The Infrared Ear Thermometer, models TM810A, TM810B, TM817, TM818, TM818A, TM819 and TM820 are substantially equivalent to the Measure Technology, models: ST613C and ST613F (K011254).

7. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of IR-04MT are as the followings:

   1> Performance Compliance Test according to ASTM E1965:2003 conducted by manufacturer
   2> Electrical Compliance Test according to IEC 60601-1 by accredited laboratory.
   3> EMC Compliance Test according to IEC 60601-1-2 by accredited laboratory.
   4> Biocompatibility Compliance Test according to ISO 10993-5 & ISO 10993-10 by accredited laboratory

8. Discussion of Clinical Tests Verification Activities Performed to Determine the Effectiveness of Device are as the followings:

   A Clinical Test Report conducted according to ASTM E1965:2003 performed by the manufacturer was included as part of ASTM E1965 conformity test report. This report was carried out in such a way that compared the accuracy performance between models TM810A, TM810B, TM817, TM818, TM818A, TM819 and TM820, as well as TM818A and the predicate device according to the method recommended in ASTM E1965 standard.

   The results of the clinical Test Report could positively support the claim of Substantial Equivalence for TM810A, TM810B, TM817, TM818, TM818A, TM819 and TM820, against the chosen 510k predicate device.

9. Conclusions:

   The Infrared Ear Thermometer, models TM810A, TM810B, TM817, TM818, TM818A, TM819 and TM820, have the same intended use and technological characteristics as the cleared device of Measure Technology, models: ST613C and ST613F (K011254). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

   In the other words, those engineering difference do not: (1) affect the intended use of ; and (2) alter the fundamental scientific technology of the device.

   Thus there are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Ke-Min Jen
Kingtech Enterprises, Limited
Farm Village
Da Ling Shan Town
Dong Guan, Guangdong China

MAY 27 2011

Re: K102935
Trade/Device Name: Infrared Ear Thermometer / Models TM810A, TM810B, TM817, TM818, TM818A TM819, and TM820
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 30, 2011
Received: May 9, 2011

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K102935

Device Name: Kingtech Enterprises Limited
KINGTECH Infrared Ear Thermometers
Models: TM810A, TM810B, TM817, TM818, TM818A, TM819, TM820

- *Indications for use:*

The KINGTECH Infrared Ear Thermometer, models: TM810A, TM810B, TM817, TM818, TM818A, TM819, and TM820 are battery-operated electronic devices with intended use of measuring body temperature from the auditory canal of a patient by means of an infrared sensor coupled with electronic signal amplification, conditioning and a digital LCD (display) unit. The devices are reusable and intended for home use on people at all ages.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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